



UNITED STATES PATENT AND TRADEMARK OFFICE

MV

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,609	06/12/2001	Shuyuan Zhang	INRP:081USD1	7626

7590 07/22/2004

Steven L. Highlander
FULBRIGHT & JAWORSKI L.L.P.
Suite 2400
600 Congress Avenue
Austin, TX 78701

EXAMINER

MOSHER, MARY

ART UNIT	PAPER NUMBER
----------	--------------

1648

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,609

Applicant(s)

ZHANG ET AL.

Examiner

Mary E. Mosher, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 3/8/2004, 4/6/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/6/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Priority

The deletion of the claim to benefit of filing dates of prior applications is noted. Note that this change makes applicant's published international application WO 00/32754 available as prior art, and removes applicant's ability to rely upon copies of references provided in earlier applications.

Double Patenting

Claims 30-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 70-104 of U.S. Patent 6,726,907 in view of March 5,552,309, for reasons of record. The provisional rejection is converted to a nonprovisional rejection, because the application has now issued as a patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30-47 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zhang et al WO 00/32734. Since applicant has deleted the claim to priority of all prior applications, this patent is available under 102(b), since it was published more than one year before the June 12 2001 filing date of this application.

Claims 30-40 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious Condon et al US 6,168,944, for reasons of record. Applicant argues that claim 31 requires a composition that has between 50 pg and 10 ng or contaminating human DNA per 1×10^{12} viral particles, and that Condon does not teach a similar purification method because some embodiments of the invention involve both filtration and chromatography whereas Condon only teaches filtration. Applicant is arguing limitations that do not appear in these claims. Regarding the difference between applicant's disclosed embodiments and Condon, these claims are not drawn to the products made by the disclosed filtration/chromatography process, but products produced by any process involving virus harvested from cells infected in mid-log culture. Since the only deficiency of Condon in regard to claim 30 and amended claims 32-35 is that Condon is silent upon the growth phase of the producer cells, there is valid reason to believe that the composition of Condon is the same as, or very similar to, the composition as it is broadly claimed. Claim 31 does not require the purified composition to meet a DNA purity requirement; the DNA purity requirement is one of 6 ALTERNATIVE properties, and the composition of claim 31 is required to have only one of the alternatives. The office action provides reasons to believe that the Condon composition meets at least the particle/PFU requirement of claims 31, 36-38, and the BSA requirement of claims 31, 39-40. Therefore, adequate justification exists to shift the burden to applicant to distinguish the claimed product-by-process composition from the prior art composition.

Claim 43 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Condon et al in view of Shabram et al WO 96/27677 (B2) or Huguhe et al (C44), for reasons of record. Applicant failed to argue this rejection, so it is maintained.

Claims 30, 31, 34, 36, 43 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Huguhe et al WO 96/27677 (B2) or Huguhe et al (C44), for reasons of record. Applicant argues that a purity limitation consistent with claim 40 is indicated in the present claims, and claim 40 was not rejected. However, this argument appears to be in error, as claim 40 involves the level of BSA contamination, and there is no BSA requirement in claims 30, 34, 36, and 43, and BSA contamination is only one alternative in the Markush group of alternative properties in claim 31.

Claims 30-38, 43 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Blanche et al WO98/00524 (B3), for reasons of record. Applicant argues that claim 41 was not rejected, and the claims recite a level of purity consistent with the level recited in claim 41. Again, this argument appears to be in error, as there is no purity limitation whatsoever in claim 30, and claims 31-38, 43 depend from either claim 30 or claim 41. Therefore, to the extent that the claims depend from claim 30, they do not require a level of purity consistent with the level recited in claim 41.

Information Disclosure Statement

The "Complaint" filed 3/8/2004 has been considered; this is not the same as the missing "C103" from 9/11/2003, which was a publication by Kraft and Tischer. Since the "Complaint" was not listed on a form 1449, it will not appear in the list of references printed on the patent face (should this application issue as a patent).

The information disclosure statement filed 4/6/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Since the claim to §120 benefit was cancelled on 3/8/2004, the provisions of Rule 1.98(d) are not applicable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1648

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

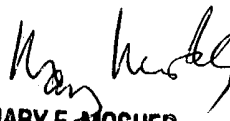
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7/21/04


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800-1600